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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,636	03/29/2004	Dennis McDevitt	022956-0692	2385
21125 7590 06/25/2008 NUTTER MCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT	PAPER NUMBER
			3733	
			NOTIFICATION DATE	DELIVERY MODE
			06/25/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/811,636

Applicant(s)

MCDEVITT ET AL.

Examiner

JERRY CUMBERLEDGE

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 29-63 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-26 and 29-63 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 02/01/2008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 12, 13, 15, 16-22, 29-35, 40-46 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US Pat. 5,209,753) in view of Bremer (US Pat. 5,209,753).

Biedermann et al. disclose an apparatus for attaching tissue to bone comprising: an expandable body (Fig. 1) defining a bore (Fig. 1, ref. 11) and configured to expand into bone (Fig. 1), said expandable body comprising a distal tip member (Fig. 1, ref. 12) and a proximal main member (Fig. 1, ref. 2), said distal tip member having a threaded recess (Fig. 1, ref. 13)(column 1, lines 56-66) in a proximal surface thereof (Fig. 1) and said proximal main member having a distally extending threaded recess (Fig. 1, ref. 11) in a proximal surface thereof and said proximal main member having a distally extending threaded projection (Fig. 1, ref. 18) threadably interengageable with the distal tip member recess; an expander pin (Fig. 1, ref. 16) comprising a shaft (Fig. 1, ref. 16) sized to be received in the bore of said expandable body and expand said expandable body laterally when said expander pin is driven into said expandable body (Fig. 1); and a tissue attachment member (Fig. 1, ref. 3) formed on said shaft; whereby when said expander pin is driven into said expandable body, said expandable body is attached to

the bone and said tissue attachment means member secures the tissue to said apparatus. The expander pin includes a fastener stabilization apparatus for stabilizing said expander pin relative to said expandable body (Fig. 1). The fastener stabilization apparatus comprises threads (Fig. 1). The tissue attachment means member comprises at least one laterally-extending projection for tacking tissue (Fig. 1, ref. 3). The at least one laterally-extending projection has as substantially linear outer edge (Fig. 1, near ref. 9). The at least one laterally-extending projection has a substantially arc-like outer edge (Fig. 1, ref. 3). The expandable body distal tip member is tapered (Fig. 1). The expandable body includes a bone securement apparatus for securing said expandable body relative to bone (Fig. 1, ref. 4). The bone securement apparatus comprises threads (Fig. 1, ref. 4). The apparatus further comprises an installation tool (column 1, lines 41-43), and wherein said installation tool comprises a shaft (column 1, lines 41-43) sized to be slidably received in said bore of said expandable body and in a bore of said expander pin. The shaft is releasably attachable to said expandable body (column 1, lines 41-43). The shaft and said expandable body are threadably interengageable with one another (Fig. 1). The shaft has a tapered distal end (Fig. 1). The shaft extends distally beyond said expandable body when said shaft is slidably received in said bore of said expandable body (Fig. 1, since the shaft extends into ref. 13). The apparatus further comprises a pusher member configured to drive said expander pin into said expandable body (column 1, lines 41-43). The pusher member slides along said shaft when driving said expander pin into said expandable body (column 1, lines 41-43).

Biedermann et al. disclose an apparatus for attaching tissue to bone comprising: an expandable body (Fig. 1) configured to expand into bone (Fig. 1), said expandable body defining a bore (Fig. 1, ref. 11); an expander pin (Fig. 1, ref. 16) comprising a shaft (Fig. 1, ref. 16) sized to be received in the bore of said expandable body (Fig. 1) and expand said expandable body laterally when said expander pin is driven into said expandable body (Fig. 1); and a tissue attachment member (Fig. 1, ref. 3) formed on said shaft; whereby when said expander pin is driven into said expandable body, said expandable body is attached to the bone and said tissue attachment member secures the tissue to said apparatus. The tissue attachment member comprises at least one laterally-extending projection (fig. 1, ref. 3) for tacking tissue. The at least one laterally-extending projection has a substantially linear outer edge. The at least one laterally-extending projection has a substantially arc-like outer edge (Fig. 1, ref. 3). The expandable body is provided with a tapered distal end (Fig. 1, ref., 7). The expandable body comprises a distal tip member (Fig. 1, ref. 12) and a proximal main member (Fig. 1, ref. 2), said distal tip member being separable from said proximal main member. The distal tip member and said proximal main member are threadedly interengageable with one another (Fig. 1). The distal tip member and said proximal main member are frictionally interengageable with one another (Fig. 1). The expandable body distal tip member is tapered (Fig. 1, ref. 7). The expandable body includes a bone securement apparatus (Fig. 1, ref. 4) for securing said expandable body relative to bone. The bone securement apparatus comprises ribs. The bone securement apparatus comprises threads (Fig. 1, ref. 4). The apparatus further comprises an installation tool (column 1,

lines 41-43) and wherein said installation tool comprises a shaft sized to be slidingly received in said bore of said expandable body and a bore of said expander pin (column 1, lines 41-43). The shaft is releasably attachable to said expandable body (Fig. 1). The shaft and said expandable body are threadedly interengageable with one another (Fig. 1). The shaft is provided with a tapered distal end (Fig. 1). The shaft extends distally beyond said expandable body when said shaft is slidingly received in said bore of said expandable body (Fig. 1). The apparatus further comprises a pusher member configured to drive said expander pin into said expandable body (column 1, lines 41-43). The pusher member slides along said shaft when driving said expander pin into said expandable body (column 1, lines 41-43). The at least one laterally-extending projection has a substantially convex configuration (Fig. 1). The at least one laterally-extending projection has a substantially planar configuration (Fig. 1, near ref. 9). The at least one laterally-extending projection has a substantially concave configuration (Fig. 1, left of ref. 11). The tissue attachment member further comprises at least one longitudinally-extending projection projecting distally out of said at least one laterally-extending projection (Fig. 2).

Biedermann et al. disclose the claimed invention except for the distal tip member being of harder material than said proximal main member.

Bremer discloses a surgical device that comprises a distal tip member that is made of a material harder than a proximal portion, in order to reduce artifacting (column 3, lines 62-68)(column 4, lines 1-12).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the distal tip member of Biedermann et al. from a harder material than the proximal main member as taught by Bremer, in order to reduce artifacting (column 3, lines 62-68)(column 4, lines 1-12).

Claims 8-10 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US Pat. 5,209,753) in view of Bremer (US Pat. 5,209,753) in view of Stone et al. (US Pat. 5,370,662).

Beidermann in view of Bremer disclose the claimed invention except for the tissue attachment member comprises a bore formed in said expander pin and a suture extending through said expander pin bore. The tissue attachment member is configured so that said suture may slide relative to said expander pin when said expander pin is received in said expandable body. The tissue attachment member further comprises a second bore formed in said expander pin and second suture extending through said second expander pin bore.

Stone et al. disclose tissue attachment means comprising a pin (Fig. 8B, entirety) with a bore (Fig. 8B, ref. 50a) formed therein, and a suture extending through the bore (column 4, lines 41-44), the tissue attachment means is configured so that the suture is slidable relative to the pin, since the sutures are merely threaded through the bores (e.g., see Fig. 1); the tissue attachment means further comprises a second bore (Fig. 8B, ref. 50a) formed in the expander pin and a second suture extending through the second expander pin bore (column 8, lines 56-58); the tissue attachment means further

comprises at least one longitudinally-extending projection (Fig. 8A, ref. 54) projecting distally out of at least one laterally-extending projection (Fig 8A, ref. 91). This bore and suture arrangement is useful for accepting a driving tool (column 6, lines 52-54).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the tissue attachment means of Beidermann in view of Bremer with the bores and sutures of Stone et al., in order to provide a suture arrangement that is useful for accepting a driving tool (column 6, lines 52-54).

Claims 11 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US Pat. 5,209,753) in view of Bremer (US Pat. 5,209,753) in view of Bonutti (US Pat. 5,948,002).

Beidermann in view of Bremer disclose the claimed invention except for the expander pin having indicia for indicating depth.

Bonutti discloses a pin (Fig. 11, ref. 92c) inserted into a bore which includes depth indicia (column 39, lines 36-38), to indicate the depth which the suture anchor has been placed into tissue (column 39, lines 26-36).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the expander pin of Beidermann in view of Bremer with the depth indicia on a pin which is inserted into a bore of Bonutti, in order for the expander pin to indicate the depth which the suture anchor has been placed into tissue.

Claims 14 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US Pat. 5,209,753) in view of Bremer (US Pat. 5,209,753) in view of Nicholson (US Pat. 5,725,529).

Beidermann in view of Bremer disclose the claimed invention except for the bone securement apparatus comprises ribs.

Nicholson discloses the bone securement apparatus (Fig. 3, ref. 10) comprising ribs (Fig. 3, ref. 16), in order to allow the bone securement apparatus to engage irregularities in the bone opening wall as the expandable member deforms and conforms to the bone opening wall during and after expansion (column 6, lines 20-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bone securement apparatus of Beidermann in view of Bremer with the ribs of Nicholson, in order to allow the bone securement apparatus to engage irregularities in the bone opening wall as the expandable member deforms and conforms to the bone opening wall during and after expansion (column 6, lines 20-24).

Claims 23-26 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US Pat. 5,209,753) in view of Bremer (US Pat. 5,209,753) in view of Moll et al. (US Pat. 5,078,718).

Beidermann in view of Bremer disclose the claimed invention except for a cannulated driver assembly (a slap-hammer), a connector for connecting the driver

assembly to a sleeve and a trigger, the driver assembly being used to apply impact tension to a sleeve.

Moll et al. discloses a cannulated driver assembly (a slap-hammer) (column 7, lines 13-15), a connector for connecting the driver assembly to a sleeve (column 7, lines 13-15) and a trigger (Fig. 3G, knob at top of device), the driver assembly being used to apply impact tension to a sleeve (column 7, lines 15-17).

It would have been obvious to a person having ordinary skill in the art at the time invention was made to have modified the apparatus of Beidermann in view of Bremer to further include a slap-hammer connected to a sleeve as taught by Moll et al., in order to apply impact tension to the expandable body of Beidermann in view of Bremer (column 7, lines 15-17).

Response to Arguments

Applicant's arguments filed 03/10/2008 have been fully considered but they are not persuasive.

With regard to Applicant's argument that the proximal and distal tip members both must be disclosed as being expandable, the examiner notes that this is not required in the claims. Claims 1 and 29 require an expandable body that can expand and the expandable body comprising various elements (e.g. a bore, a distal tip member, a proximal main member). The expandable body of the device has at least a portion that can expand (abstract), at thus can be considered to be expandable. The remaining

portions of the device (*e.g.* a bore, a distal tip member, a proximal main member) are not required to be expandable.

With regard to Applicant's argument that the threaded projection is not part of the expandable body, the examiner respectfully disagrees. While the threaded projection may not be *monolithic* with the body, it can still be considered *part* of the body. The threaded projection is connected to the body when the device is used and can be considered to be part of the body when in use.

With regard to Applicant's arguments directed to the tissue attachment member being formed on the expander pin, it is noted that the examiner is treating this as a product by process recitation. It is noted that the device of Biedermann et al. appears to be substantially identical to the device claimed, although produced by a different process (*i.e.* the tissue attachment means is attached on the shaft of the device when the device is assembled), therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

With regard to Applicant's argument that the device of Biedermann cannot perform the function of "when said expander pin is driven into said expandable body , said expandable body is attached to the bone and said tissue attachment member secures the tissue to the apparatus," the examiner respectfully disagrees. When viewed from the opposite end of the device, the pin is being driven into the body from the distal end of the device toward the proximal end of the device by the action of the threads (Fig. 1)(column 2, lines 19-29).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733